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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,809	02/05/2004	Joel E. Bernstein	812540-610001	5946

28104 7590 07/28/2005

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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/772,809

Applicant(s)

BERNSTEIN, JOEL E.

Examiner

Abigail M. Cotton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/5/04, 3/1/04, 5/19/04 and 6/23/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/1/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 9-15 in the reply received on June 23, 2005 is acknowledged.

Claims 1-15 are pending in the application, with claims 1-8 being withdrawn from further consideration as being drawn to a non-elected invention.

Claim Objections

Claim 13 is objected to because the phrase "administered in a dosage for from about 0.50 gms" is grammatically incorrect. The Examiner respectfully suggests replacing "for from" with "of from."

Claim 14 is objected to because of the abbreviated term "NSAIDs." It is a requirement that the first occurrence of an abbreviation follow the term as completely spelled out. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/50044 to Frank S. Caruso, published November 12, 1998.

Caruso teaches treating neuropathic pain with a composition having an antidepressant (see abstract, in particular.) Caruso teaches that the antidepressant can be a tricyclic antidepressant such as imipramine hydrochloride, doxepin hydrochloride, among others (see page 4, lines 1-19, in particular.) Caruso teaches that an oral method of administration can be employed, and the composition may be provided as tablets or hard capsules, which are pharmaceutically acceptable vehicles (see page 6, lines 5-12, in particular.) Caruso furthermore teaches that the composition can have a non-narcotic analgesic such as acetaminophen or naproxen (see page 7, lines 10-24, in particular.)

Regarding claims 9-15, Caruso teaches exemplary tablet dosage forms having antidepressant drugs and an additional active component that is a non-narcotic

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analgesic (see page 10, lines 5-37, in particular.) Regarding claims 11-12 and 14-15, Caruso teaches that the tablet form can comprise compositions with 25 mg of imipramine hydrochloride and 325 mg of aspirin or acetaminophen (see examples 36 and 37, in particular.) Thus, Caruso teaches the composition having the claimed tricyclic antidepressant compounds and non-narcotic analgesics, and also teaches the claimed pharmaceutically acceptable vehicle.

Regarding claims 9-10, Caruso's teaching of 25 mg of imipramine hydrochloride is considered to meet the limitation of being a "low dose" of tricyclic antidepressant compound as claimed, because it falls within the range of "about 25 mg/day or less," in accordance with the definition of the "low dose" as set forth by Applicants in the first full paragraph on page 3 of the specification. Caruso's teaching thus also meets the limitation of being from "about" 2.5 mg to "about" 25 mg daily as recited in claim 10.

Regarding claims 9 and 13, Caruso's teaching of 325 mg of acetaminophen is considered to meet the limitation of being a "standard dose" of non-narcotic analgesic compound as claimed, because it falls within the range of "about 0.5 grams to about 2.6 grams," in accordance with the Applicants' guidance of a suitable "standard dose," which is set forth in the second full paragraph on page 3 of Applicants' specification. In particular, 325 mg of acetaminophen is considered to be within the range of "about" 0.5 grams to "about" 2.6 grams, as set forth by Applicants.

Accordingly, the tablet dosage forms taught by Caruso anticipate the compositions of claims 9-15.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In particular, U.S. Patent No. 4,579,846 to Crawford et al. teaches composition for treating inflammation comprising piroxicam and the antidepressant doxepin.

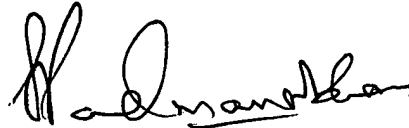
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 8:30-5:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER